UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,754	09/23/2005	Michael Buschle	SONN:076US	1380

32425 7590 07/01/2008

FULBRIGHT & JAWORSKI L.L.P.
600 CONGRESS AVE.
SUITE 2400
AUSTIN, TX 78701

EXAMINER	
LE, EMILY M	

ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
07/01/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/550,754	BUSCHLE ET AL.	
	Examiner	Art Unit	
	Emily Le	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09/23/05+04/21/08*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04/17/07+05/11/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I in the reply filed on 04/21/2008 is acknowledged.

Status of claims

2. Claims 1-12 and 23-28 are canceled. Claims 13-22 are pending and under examination.

Sequence Compliance

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below.

The claims contain amino acid sequence(s) encompassed by the sequence requirements of 37 CFR 1.821 through 1.825. For example, the amino acid sequence recited in claim 20 is not accompanied by a sequence identifier.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites a dependency to itself. This is improper. It is unclear as to what Applicant intends to encompass by the claim because it depends on itself rather than any other claim. For the purpose of advancing examination, the claim has been interpreted to depend on claim 17.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 13-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fritz et al.[1] in view of Egyed et al.[2]

The claims are directed to a composition comprising an antigen, a peptide, and an immunostimulatory oligonucleotide, wherein the peptide and oligonucleotide have the structures described in the claims. Claim 14, which depends on claim 13, requires that the peptide be 11 amino acid residues in length by designating variable N to be 5. Claim 13, which depends on claim 13, requires the composition to further comprise alum adjuvant. Claim 16, which depends on claim 13, requires the antigen to be a viral antigen. Claim 17, which depends on claim 16 requires the viral antigen to be an influenza virus antigen, HCV antigen, HBV antigen, HIV antigen, HPV antigen, JEV antigen, a combined antigen or a combination of one or more the listed antigens. Claim

[1] Fritz et al. WO 02/32451 A1, published April 25, 2002.
[2] Egyed et al. WO 01/93903 A1, published December 13, 2001.

18, which is interpreted to depend on claim 17, which requires the influenza antigen to be a hemagglutinin and neuraminidase antigens. Claim 19, which depends on claim 13, requires the composition to further comprise a polycationic peptide. Claim 20, which depends on claim 13, requires the peptide to be Peptide A, which has the amino acid sequence of: $KLKL_5KLK$ and the oligonucleotide be $d(IC)_{13}$. Claim 21, which depends on claim 13, requires the composition to further comprise an oligonucleotide comprising a CpG motif. Claim 22, which depends on claim 13, requires the composition to comprise a polycationic peptide and an oligonucleotide comprising a CpG motif.

Fritz et al. teaches a composition comprising an antigen and a peptide. The antigen that Fritz et al. teaches includes the following viral antigens: influenza virus, HCV, HBV and HIV antigens. The peptide that Fritz et al. teaches has the same formula as those described in the claims of the instant patent application. The peptide of Fritz et al. has the following amino acid sequence: $KLKL_5KLK$.

Fritz et al. also suggests the addition of immunostimulating/immunogenic nucleic acid, such as an oligodeoxynucleotide containing deoxyinosine, an oligodeoxynucleotide containing deoxyuridine, an oligodeoxynucleotide containing the CpG motif or an inosine and cytidine containing nucleic acid molecule.

Thus, at the time the invention was made, it would have been prima facie obvious for one of ordinary skill in the art to include immunostimulating/immunogenic nucleic acid, such as an oligodeoxynucleotide containing deoxyinosine, an oligodeoxynucleotide containing deoxyuridine, an oligodeoxynucleotide containing the CpG motif or an inosine and cytidine containing nucleic acid molecule in the

composition of Fritz et al. One of ordinary skill in the art, at the time the invention was made would have been motivated to do so to modify the immune response induced by the composition of Fritz et al. One of ordinary skill in the art, at the time the invention was made would have had a reasonable expectation of success for doing so because the immunostimulatory activities of said oligonucleotides are well known in the art.

While Fritz et al. does suggest the addition of an oligonucleotide comprising an inosine and cytidine, Fritz et al. was not specific on the length of the oligonucleotide. As recited in the claims, the oligonucleotide is about 5 to 151 nucleic acid residues in length. It should also be noted that Fritz et al. also suggests the addition of a polycationic peptide with the composition.

However, the deficiency noted in Fritz et al. is fully compensated by Egyed et al. Egyed et al. teaches an oligonucleotide comprising inosine and cytidine. The oligonucleotide Egyed teaches is a 26 nucleic acid residue oligomer, which is poly $d(IC)_{13}$. Egyed et al. additionally teaches that the oligonucleotide, in combination with a polycationic peptide, served as adjuvants to effectively deliver peptide antigens to the immune system.

Thus, it would have been prima facie obvious for one of ordinary skill in the art, at the time the invention was made to combine the teachings of Fritz et al. and Egyed et al. to arrive at the claimed invention. One of ordinary skill in the art, at the time the invention was made, would have been motivated to do so to modulate, preferably enhance, the immune response induced by the composition of Fritz et al. One of ordinary skill in the art, at the time the invention was made, would have had a

reasonable expectation of success for doing so because the use of adjuvants in compositions are routinely practiced in the art.

Additionally, while Fritz et al. does suggest the addition of any known adjuvants, Fritz et al. does not specifically suggests alum $Al(OH)_3$. However, the deficiency noted in Fritz et al. is fully compensated by Egyed et al. Egyed et al. evidences the use of alum as an adjuvant at the time the invention was made. Thus, it would have been prima facie obvious for one of ordinary skill in the art, at the time the invention was made, to add alum to the composition of Fritz et al. One of ordinary skill in the art, at the time the invention was made, would have been motivated to do so to modulate, preferably enhance, the immune response induced by the composition rendered obvious by Fritz et al. and Egyed et al. One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because the use of adjuvants in compositions are routinely practiced in the art.

Lastly, while Fritz et al. does teaches of viral antigens, including antigens derived from the influenza virus, Fritz et al. does not specifically suggest that the antigen be a hemagglutinin or neuraminidase antigen. However, as Fritz et al. noted, any antigen can be used with the composition, and it is well known in the art that hemagglutinin or neuraminidase antigens can readily be attained from influenza virus. Thus, it would have been prima facie obvious for one of ordinary skill in the art to use hemagglutinin or neuraminidase antigens as the antigen in the composition of Fritz et al. One of ordinary skill in the art would have been motivated to do so to induce an immune response against the influenza virus. One of ordinary skill in the art, at the time the invention was

made would have had a reasonable expectation of success for doing so because the substitution of one antigen for another is routinely practiced in the art.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 13-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 39 of copending Application No. 10/339442 in view of Egyed et a. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The claimed invention is directed to a composition comprising an antigen, a peptide, and an immunostimulatory oligonucleotide of 5-151 nucleic acid residues in length, wherein the peptide and oligonucleotide have the structures described in the claims.

The claim of the copending patent application is directed to a composition comprising an antigen, a peptide, and an immunostimulatory oligonucleotide. The peptide described in the copending patent application is the same as the peptide recited in the claimed invention. The oligonucleotide of the copending patent application has the same formula as those described in the claims of the instant patent, with the exception that the oligonucleotide recited in the copending application does not have a specific oligonucleotide length.

However, Egyed et al. teaches an oligonucleotide comprising inosine and cytidine. The oligonucleotide Egyed teaches is a 26 nucleic acid residue oligomer, which is poly $d(IC)_{13}$. Egyed et al. additionally teaches that the oligonucleotide, in

combination with a polycationic peptide, served as adjuvants to effectively deliver peptide antigens to the immune system.

Thus, it would have been prima facie obvious for one of ordinary skill in the art, at the time the invention was made to combine the teachings of Egyed et al. and the copending patent application to arrive at the claimed invention. One of ordinary skill in the art, at the time the invention was made, would have been motivated to do so to modulate, preferably enhance, the immune response induced by the composition of the copending patent application. One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because the use of adjuvants in compositions are routinely practiced in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 13-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 69 of copending Application No. 10/478771. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The claim of the copending patent application is directed to a composition comprising an antigen, a peptide, and an immunostimulatory oligonucleotide. The immunostimulatory oligonucleotide described in the copending patent application is the same as the immunostimulatory oligonucleotide recited in the claimed invention.

The difference between the claims of the copending patent application and the claims of the instant patent application is: It is not readily apparent if the peptide

described in claim 69 of the copending application is the same as the peptide recited in the claims of the patent application. Thus, the Office turned to the specification to learn what Applicant intends to encompass by the peptide recited in the claims of the copending application. It is found that, in the copending patent application, Applicant intends to encompass a peptide that is the same as those recited in the claims of the instant patent application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claims 13-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 42 and 50 of copending Application No. 10/297555. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claim 42 of the copending patent application is directed to a composition comprising an antigen and an immunostimulatory oligonucleotide. The immunostimulatory oligonucleotide described in the copending patent application is the same as the immunostimulatory oligonucleotide recited in the claimed invention.

The difference between the claims of the copending patent application and the claims of the instant patent application is: Claim 42 of the copending patent application does not comprise a peptide. However, claim 50 of the copending patent application does suggest the addition of a peptide. The specification teaches that the peptide is immunostimulatory. Thus, it would have been prima facie obvious for one of ordinary skill in the art to include the peptide of claim 50 in the composition of claim 42. One of

ordinary skill in the art would have been motivated to do so to modify the immune response induced by the composition of claim 42.

The difference between the claims of the copending patent application and the claims of the instant patent application is: It is not readily apparent if the peptide described in claim 50 of the copending application is the same as the peptide recited in the claims of the patent application. Thus, the Office turned to the specification to learn what Applicant intends to encompass by the peptide recited in the claims of the copending application. It is found that, in the copending patent application, Applicant intends to encompass a peptide that is the same as those recited in the claims of the instant patent application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 13-21 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 7148191 in view of Fritz et al. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The claim of the copending patent application is directed to a composition comprising an antigen, a peptide, and an immunostimulatory oligonucleotide. The immunostimulatory oligonucleotide described in the copending patent application is the same as the immunostimulatory oligonucleotide recited in the claimed invention.

The difference between the claims of the copending patent application and the claims of the instant patent application is: The polycationic peptide described in the

copending patent application is not the same as the peptide recited in the claims of the instant patent application. However, at the time the invention was made, Fritz et al. teaches of polycationic peptides that have adjuvant properties. Thus, it would have been prima facie obvious for one of ordinary skill in the art to substitute the polycationic peptide of the copending patent application. One of ordinary skill in the art, at the time the invention was made would have been motivated to do so to produce an immunostimulatory composition. One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because the substitution of known alternatives are routinely practiced in the art.

Conclusion

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571)272-0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Emily Le/
Primary Examiner, Art Unit 1648

/E. L./